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Characterization of oral disintegrating film of peanut skin extract—Potential route for buccal delivery of phenolic compounds

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ABSTRACT

This paper aimed to develop and characterize oral disintegrating films (ODF) based on gelatin and hydroxypropyl methylcellulose (HPMC) incorporated with peanut skin extract (PSE) as phenolic compounds vehicle. Films were prepared by casting technique varying the polymer ratio (GEL:HPMC 100:0, 25:75, 50:50, 75:25, 0:100) and PSE concentration (20 and 30 g/100 g film-forming solution). Formulations with high content of gelatin presented insoluble complex possibly due to cross-linking between gelatin and polyphenols. For formulations which gelatin was in a minority or equal concentration of HPMC, the increase in the PSE concentration favored the association of rich phases in gelatin and HPMC. This also increased inter- and intramolecular bonding which led to a more compact matrix and reduction of films elongation and tensile strength around 45%. The HPMC film with PSE (20%) presented tensile strength of 26.63 ± 1.89 MPa, elongation of $4.97 \pm 0.41\%$, contact angle of $67.17 \pm 0.41^{\circ}$ and disintegration time of 17.87 ± 1.77 s. In the *in vitro* release profile, 80% of phenolics were released in 5 min, and in accelerated stability test the films retained 60% of the total phenolic compounds. HPMC-based film can be a good alternative to vehicle the active compounds present in peanut skin.

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1. Introduction

There is increasing evidence that consumption of phenolic compounds present in natural foods can reduce the risk of serious health disorders because of their antioxidant activity [1]. The use of industrial by-products as source of phytochemicals is an economically viable and environmentally alternative [2].

Peanut skin obtained after blanching is a residue of the food industry, which is related to the presence of bioactiove compounds, such as daidzein, genistein, trans-resveratrol, quercetin, rutin, catechins and procyanidins [3–5]. Bansode et al.[6] demonstrated that polyphenols present in aqueous extract of peanut skin caused a significant reduction in body weight, epididymal fat, plasma and liver triglyceride and cholesterol levels in rats that received a diet rich in cholesterol and lipids.

Bansode et al. [7] also confirmed that polyphenols from peanut skin may confer a key role of hypolipidemic effect. The authors found that peanut skin extract supplemented in addition to oil gavage resulted in significant decrease in very-low-density-lipoprotein (VLDL) and triglyceride in plasma within 5 h. In the same study, for rats receiving a Western diet type for 5 weeks with peanut skin extract (150 and 300 mg/kg body weight) was observed a reducing of blood lipid and plasma fatty acids profile [7].

Tsujita, Shintani and Sato [8] found that the polyphenols present in peanut skin exhibit strong inhibitory activity of α-amylase which can retard absorption of carbohydrates; according to the authors oral administration of the polyphenol fraction of peanut skin for rats fed with corn starch significantly suppressed an increase in blood glucose levels.

On the other hand, the phenolic compounds oral administered have poor bioavailability due to glucuronidation catalyzed by UDP-glucuronosyltransferases enzymes (UGTs) which occur in the first-pass in the gut and liver, which hinders the effectiveness of these compounds as therapeutic agents [9]. The bioavailability is a critical factor to determine the efficacy of bioactive compounds orally ingested, therefore it is necessary to develop different delivery systems to enhance the in vivo bioavailability of nutraceuticals orally administered [10].

Oral disintegrating film (ODF) is a dosage form produced with water-soluble polymers and when placed in oral cavity, it is quickly hydrated by saliva, adhere to mucosa and disintegrate in seconds releasing the active ingredient for oromucosal absorption, which

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results in a rapid absorption and instant bioavailability due to high blood flow regions such as the sublingual, for example [11].

Thus, the oromucosal absorption may increase the bioavailability of many compounds present in peanut skin. Therefore, the purpose of this study is to develop and characterize oral disintegrating films based on gelatin and hydroxypropyl methylcellulose, additivated with peanut skin extract aiming to vehicle polyphenols through the oral mucosa.

2. Experimental

2.1. Materials

The peanut skin Runner (variety IAC886) obtained by bleaching process, was donated by the Cooperativa dos Plantadores de Cana da Zona de Guariba (COPLANA) (Jaboticabal, SP, Brazil). Gelatin (260 Bloom/40 mesh) and hydroxypropyl methylcellulose (HPMC E15) were donated by Gelnex (Itá, Santa Catarina, Brazil), and Colorcon (West Point, Pennsylvania, USA), respectively. Sorbitol (plasticizer) was purchased from Vetec (Rio de Janeiro, RJ, Brazil) and ethanol from Synth (Diadema, Brazil).

2.2. Production of peanut skin extract

Peanut skin was manually selected using a sieve (10 mesh) to remove the peanut fragments. The fraction not retained on the sieve was discarded because of the excessive amount of peanut fragments. The retaining material was manually selected to remove remaining fragments of peanuts. The resulting material was used for extraction.

The peanut skin extract (PSE) was performed using parameters previously defined by Nepote, Grosso and Guzmán [12]. Peanut skin (20 g) was dispersed in 400 mL of ethanol (70%). The dispersion was maintained under mechanical stirring (RW20 digital, IKA, Germany) at 500 rpm for 10 min (room temperature). The residue was subjected to two more extractions under the same conditions. The resulting extract of the three consecutive extractions was concentrated in a rotaevaporator (IKA, Campinas, SP, Brazil) at 40 °C according to the proposed by Duh and Yen [13] under vacuum to reach 30% of the initial volume. The extract was refrigerated overnight, and then filtered through Whatman filter paper n° 1 and Sartorius glass fiber membrane (47 mm), to eliminate any suspension particles and small lipid fractions. Until incorporation in the films, the filtered solution was stored at refrigerator.

2.3. Oral disintegrating film production

The films were produced by casting technique. Gelatin (GEL) and hydroxypropyl methylcellulose (HPMC) were used as film-forming polymers and five formulations were studied on the following reasons (GEL: HPMC): 0:100, 25:75, 50:50, 75:25, 100:0. The concentration of polymers (GEL + HPMC) was kept constant at 2 g/100 g film-forming solution; sorbitol was used as plasticizer in the concentration 20 g/100 g polymer and peanut skin extract (PSE) has been incorporated in the concentrations of 20 and 30 g PSE/100 g film-forming solution.

The film-forming solution of gelatin was prepared by hydrating in distilled water for 30 min at room temperature and then solubilizing it in thermostatic bath (MA 127, Marconi, Piracicaba, SP, Brazil) at 50 °C temperature (10 min). The film-forming solution of hydroxypropyl methylcellulose was prepared by dispersing HPMC in distilled water at 90 °C, followed by magnetic stirring for 30 min. The blends were produced by mixing the film-forming solution of gelatin and hydroxypropyl methylcellulose under magnetic stirring (room temperature, 30 min). Sorbitol, previously dissolved, was incorporated into the film-forming solution under magnetic stirring (10 min) and then the PSE was incorporated under the same conditions. Constant mass of the film-forming solution was cast onto plates (12 × 12 cm), and the drying of the film-forming solution held in forced circulation oven (MA-035, Marconi, Piracicaba, SP, Brazil) at 30 °C for 24 h. The thickness of the films was controlled by the mass of film-forming solution per area of the support and kept constant at 0.050 ± 0.005 mm. After drying, it was determined using a Digimatic Micrometer (Mitutoyo, Tokyo – Japan). The films were placed in desiccators containing silica at room temperature for 10 days for the analysis of infrared spectroscopy and scanning electron microscopy. For other characterization tests films were maintained in desiccators at 58% relative humidity (saturated NaBr) and room temperature (25 °C) for 5 days.

2.4. Scanning electron microscopy (SEM)

The cross-section morphology of the films was evaluated using a scanning electron microscope TM300 (Hitachi, Japan). To facilitate the observation, the films were broken after immersion in liquid nitrogen. Samples were fixed to the surface of the holder using double sided adhesive tape and images were captured using a 3000 x magnification and acceleration voltage of 15 kV.

2.5. Color

The color parameters of the films were determined according to Gennadios et al. [14]. The films were superimposed on a standard white ($L^* = 93.624$, $a^* = -0.824$ and $b^* = 1.236$) and using a colorimeter Miniscan XE (HunterLab) with D65 illuminant and 10° opening, the coordinates lightness (L*), chroma a* and chroma b* were obtained.

2.6. Surface pH

The surface pH was determined according to Prabhu et al. [15] adapted using phosphate buffer saline (pH 6.75) prepared according to Wong, Yuen and Peh [16] as simulated saliva solution. Sample film (3 × 2 cm) was placed in a container containing 0.5 mL of buffer solution. After 30 s (immersion film), the pHmeter electrode (pH 3210, WTW, Weilheim, Germany) was placed in contact with the film surface for 1 min, and then the pH value was recorded.

2.7. Fourier transform infrared spectroscopy (FTIR)

The Fourier transform infrared spectroscopy was performed on a Spectrum One spectrometer (Perkin Elmer, Waltham, MA, USA) with universal attenuated total reflectance (UATR) accessory at room temperature. 16 scans were performed for each sample in the spectral range 650–4000 cm^{-1} with a resolution of 2 cm^{-1}.

2.8. Mechanical properties

Mechanical properties are necessary to evaluate sufficient strength to withstand mechanical damage of films during the production, handling and application [17]. These properties of oral disintegrating films were evaluated using a TA.XTplus texture analyser (Stable Micro Systems, Godalming, Surrey, UK) equipped with a 50 kg load cell. The test parameters were set according to ASTM method [18]. Samples with dimensions of 25 × 100 mm were fixed to the tensile grips (initial distance of separation = 100 mm) and subjected to traction (constant speed of 50 mm/min). From the stress-strain curve, it was determined the tensile strength (MPa) and elongation (%) of film.

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